AUG 14 2007

K070622

1. SPECIAL 510(k) DEVICE MODIFICATIONS SUMMARY

510(k) Number: TBD

Applicant Information:

Date Prepared: December 12, 2006

Name: NeoGuide Systems, Inc.
Address: 104 Cooper Court
Los Gatos, CA 95032
Phone: 408-399-9999
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Contact Person: Jorge L. Porras
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Facsimile Number: (408) 399-3386

Device Information:

Classification: Class II
Trade Name: NeoGuide Endoscopy System
Common Name: Colonoscopy System
Classification Name: Colonoscope, 78 FDF / 21 CFR 876.1500

Predicate Devices:

The indication for use, operating principle, basic technology, physician interface and same contacting materials of the NeoGuide Endoscopy System, are equivalent to the Navigator Endoscopy System previously cleared under 510(K) K052930. Additional predicate devices are listed below:

K001241 - Olympus Optical Co, Ltd. EVIS EXERA Colonovideoscope
K961563 - Pentax Precision Instrument Corporation EC3840TL, Video Colonoscope
K032688 - Sightline, Colonosight, Video Colonoscope
K033954 - USGI Shape Locking Endoscopic Overtube

Device Description:

The NeoGuide colonoscope is manually inserted and withdrawn by the physician, who steers and controls it using the electromechanical controls located at the handle. The colonoscope distal tip is equipped with a CCD camera and fiber optic illumination bundles for procedural illumination and includes a standard tool channel for therapeutic procedures. Valves control insuflation air, water irrigation, and suction.

The NeoGuide Colonoscope incorporates fifteen active electro-mechanically controlled segments, not including the tip. During a procedure, the segments shape conforms to the path defined by the physician as the tip is manually steered but electromechanically controlled through the colon lumen. Each of the active segments uses four control cables to articulate in the up/down and left/right directions. This mechanism of action is the same as the mechanism used in conventional colonoscope steerable tips. The NeoGuide Endoscopy System displays a graphical representation of the system interpretation of the tip movements commanded by the physician and the depth of insertion of the colonoscope into the patient.

Intended Use:

The NeoGuide Navigator Endoscopy System is intended to provide visualization and diagnostic / therapeutic access to the adult lower gastrointestinal tract (including, but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery.

Comparison to Predicate Device(s):

The NeoGuide Colonoscope is similar to the predicate listed, K052930, including indications for use, the same operating principle, the same basic technology and several of the same contacting materials, and physician interface. The NeoGuide Endoscopy System is designed for use in the same manner as existing colonoscopes. However, the electromechanical actuation of the segments is replicated at the tip. The colonoscope features a physician controlled electromechanically actuated tip using the same conventional pull wire system used to steer the Navigator Endoscopy System. As with the predicate device, the NeoGuide Colonoscopy System allows mechanical control of the insertion tube shape and reproduction of the directional path established by the physician.

Summary:

Based upon the intended use, descriptive information, and performance evaluation the NeoGuide Endoscopy System is substantially equivalent to predicate devices and does not pose any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 14 2007

NeoGuide Systems, Inc.
c/o Mr. Tamas Borsai
Division Manager, Medical Division
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTON CT 06470

Re: K070622
Trade/Device Name: NeoGuide Endoscopy System
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF
Dated: July 23, 2007
Received: July 26, 2007

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070622

Device Name: NeoGuide Endoscopy System and Accessories

Indications For Use:

The NeoGuide Endoscopy System is intended to provide visualization and diagnostic / therapeutic access to the adult lower gastrointestinal tract (including, but not limited to, the anus, rectum, sigmoid colon, colon, cecum and ileocecal valve) for endoscopy and endoscopic surgery.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070622